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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,180	05/30/2007	**Gerd Wagner**	15111.0087	4526

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,180	WAGNER ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 17, drawn to an oligonucleotide and the use thereof. Group I encompasses **multiple inventions**, as indicated below.

Group II, claim(s) 2-10, drawn to a microarray device. Group II is further subject to a **species election**, as indicated below.

Group III, claim(s) 11-16 and 18-19, drawn to a method of bacterial detection. Group III is further subject to a **species election**, as indicated below.

2. It is noted that claim 10 is an improper multiple dependent claim, as it depends from and requires elements from 2 different claims (dependent claims may refer to other claims in the alternative only). The claim has been grouped with Group II, as it is directed to a device. If Group II is elected, claim 10 should be amended if applicant wishes to have it fully considered.

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. Group I requires a single oligonucleotide selected from those recited in claim 1. Although Group II includes one claim (claim 10) that improperly depends from claim 1 and embraces devices including multiple oligonucleotides selected from those of claim 1, Group II also broadly encompasses microarray devices taught in the prior art as exemplified by Wagner et al

(Journal of Bacteriology 185(7):2085-2095 [April 2003]; cited in IDS). Accordingly, as Group II does not make a contribution over the prior art, it lacks a special technical feature under PCT Rule 13.2. Similarly, while the generic device of Group II may be employed in the methods of Group III (see text of claim 11), a shared special technical feature is lacking with respect to Groups II-III because that device does not make a contribution over the prior art (again see Wagner et al). Groups I and III do not share any features that could constitute a special technical feature under PCT Rule 13.2. Accordingly, unity of invention is lacking with regard to Groups I-III.

4. It is noted that MPEP 1850 states that:

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.
In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Further restriction applicable to Group I

5. With further regard to **Group I**, this Group encompasses numerous different oligonucleotides recited in the alternative only (it is noted that claim 1 specifically requires a single oligonucleotide selected from the recited group). Each of the oligonucleotides possesses a "common property or activity" in that each can be used for genotyping *P. aeruginosa*. However, the different oligonucleotides are specific for detection of different polymorphisms/genotypes. The claims embrace several pairs of oligonucleotides that target the 2 different variants of a specific polymorphism, such that these pairs of oligonucleotides do possess a significant structural element/framework in common (for example, SEQ ID NOS 72-73, SEQ ID NOS 76-77, etc.). Although the claims as written are directed to single oligonucleotides, such pairs are considered as meeting the criteria of being "of a similar nature" and will be treated as one invention. However, the various pairs and other individual oligonucleotides embraced by the claims that lack such structural similarity with respect to one another are not "of a similar nature" and lack unity of invention with one another. These oligonucleotides do not share a significant structural element with one another and do not function in the same way (as they target different sequences/variations), and are thus deficient with respect to both (B)(1) and (B)(2) noted above. Accordingly, each oligonucleotide/structurally similar pair of oligonucleotides embraced by Group I constitutes a separate invention. **If Group I is elected**, applicant should further specify and elect either a single oligonucleotide, or a single pair of structurally similar oligonucleotides (i.e., a pair targeting the 2 variants of the same polymorphic sequence).

Species elections applicable to Groups II-III

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) With regard to **Group II**, the numerous different combinations of multiple oligonucleotides, each of which constitutes a separate species (see text of claim 2 and of dependent claim 10, which claims require the selection of multiple oligonucleotides from those of claim 1).

b) With regard to **Group III**, the numerous differ combinations of multiple primers, each of which constitutes a separate species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The claims are deemed to correspond to the species listed above in the following manner:

Regarding **Group II**, each combination of probes selected from those recited in claim 1 constitutes a separate species (see text of claims 2 and 10). Claim 2 is considered generic with respect to the invention of Group II.

Regarding **Group** III, each combination of primers selected from those recited in dependent claim 16 constitutes a separate species. Claims 11-12 are considered generic with respect to the invention of Group **III**.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a) Regarding **Group II**, this Group encompasses numerous different combinations of multiple oligonucleotides. Each such combination of oligonucleotides possesses a "common property or activity" in that each combination can be used for genotyping *P. aeruginosa*. However, the different oligonucleotide combinations are specific for detection of different combinations of polymorphisms/genotypes. Thus, each combination differs both structurally and functionally as compared to each other combination embraced by the claims, and these combinations are therefore deficient with respect to both (B)(1) and (B)(2) noted above. Accordingly, each device comprising a particular combination of oligonucleotides as embraced by Group II constitutes a separate species of the generic invention of claim 2. **If Group II is elected**, applicant should further specify and elect a single combination of oligonucleotides selected from the list presented in claim 1.

b) Regarding **Group III**, this Group encompasses numerous different combinations of multiple primers. Each such combination of primers possesses a "common property or activity" in that each combination can be used for amplification of *P. aeruginosa* nucleic acids. However, the different primer combinations are each

characterized by different structures/sequences and are specific for amplification of different targets. Thus, each combination differs both structurally and functionally as compared to each other combination embraced by the claims, and these combinations are therefore deficient with respect to both (B)(1) and (B)(2) noted above. Accordingly, each combination of primers embraced by Group III constitutes a separate species of the generic invention of claims 11-12. **If Group III is elected**, applicant should further specify and elect a single combination of primers selected from the list presented in claim 16.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

571/272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634